

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

RALPH C. NEAL,

Civil Action No. 08-C-0464

Plaintiff,

Judge: William C. Greisbach

v.

CHRISTOPHER & BANKS
COMPREHENSIVE MAJOR MEDICAL
PLAN, CHRISTOPHER & BANKS GROUP
DISABILITY INCOME INSURANCE
PLAN, and CHRISTOPHER & BANKS,
INC.

**DEFENDANT’S PROPOSED
FINDINGS OF FACT IN
SUPPORT OF ITS MOTION
FOR SUMMARY JUDGMENT**

Defendants.

Pursuant to Local Rule 56.2(a), Defendants Christopher & Banks Comprehensive Major Medical Plan (the “Plan”) and Christopher & Banks, Inc. (“Christopher & Banks”) submit these Proposed Findings of Fact in support of its Motion for Summary Judgment on the Administrative Record, seeking dismissal with prejudice of Count I.¹ Each Proposed Finding of Fact is supported herein with a specific citation to evidentiary materials in the Administrative Record. Except as otherwise noted, all supporting documents are attached as Exhibits to the Declaration of Glenn Salvo in Support of Defendant’s Motion for Summary Judgment on the Administrative Record, [“Salvo Decl. ¶ _”].

¹ Count II is being dismissed by Stipulation without prejudice.

A. Mr. Neal Participated in a Self-Funded ERISA Employee Welfare Benefit Plan Through Christopher & Banks.

1. The Plan is a self-funded ERISA employee welfare benefit plan, within the meaning of 29 U.S.C. § 1002(1). *See, e.g.*, Second Amended Complaint, ¶ 2; Christopher & Banks Comprehensive Major Medical Plan, dated December 1, 2005, at 83 (CB 000091) [Salvo Decl. ¶ 2(a)] (hereinafter the “Plan”).

2. As Plan Administrator, the Plan gives Christopher & Banks the following discretionary authority:

The plan administrator shall have the sole discretionary authority to determine eligibility for plan benefits or to construe the terms of the plan, and benefits under the plan will be paid only if the plan administrator decided in its discretion, that the participant or beneficiary is entitled to such benefits.

Id. at 79 (CB 000087).

3. Christopher & Banks contracts with Coventry Health Care (“Coventry”) to perform claims processing and other specified services in relation to the Plan.² *Id.* at 79 and 89 (CB 000087 and 000097).

4. The Plan states that “benefits are not provided for certain kinds of treatments or services, even if your *health care provider* recommends them.” *Id.* at 14 (CB 000022).

² At the beginning of the relevant time period, the Plan contracted with First Health to perform these services. First Health was later acquired by Coventry Health Care. For simplicity, these Proposed Findings of Fact, consistent with the Memorandum in Support of Summary Judgment, will refer to both First Care and Coventry as “Coventry.”

5. In particular, the Plan explains that some transplant services are not covered, including “Services that are considered *investigational/experimental* or not *medically necessary*.” *Id.* at 32 - 33 (CB 000040-41).

6. The Plan defines “medically necessary” as follows:

Medically necessary services and/or supplies the *plan administrator* determines, in the exercise of its discretion, to be:

1. Medically appropriate, which means that the expected health benefits (such as increased life expectancy, improved functional capacity, prevention of complications, relief of pain) exceed the expected health risks by a sufficiently wide margin;
2. Necessary to meet the basic health needs of the patient as a minimum requirement;
3. Rendered in the most cost-efficient manner and setting appropriate for the delivery of the health service;
4. Consistent in type, frequency and duration of treatment with scientifically-based guidelines of national medical research, professional medical specialty organizations or governmental agencies that are accepted by the plan;
5. Consistent with the diagnosis of the condition;
6. Required for reasons other than the comfort or convenience of the patient or his or her *physician*; and
7. Of demonstrated value based on clinical evidence reported by peer reviewed medical literature and by generally recognized academic medical experts; that is, it is not *investigational/experimental*.

Id. at 76 (CB 000084).

7. The Plan’s multi-part definition of “medically necessary” specifies that a “treatment, procedure, service or supply must meet all of the criteria listed above to be considered medically necessary and to be eligible for coverage under this plan.” *Id.*

8. The Plan defines “investigational/experimental” as follows:

A health product or service is deemed experimental if one or more of the following criteria are met:

- * Any drug not approved for use by the FDA; any drug that is classified as IND (investigational new drug) by the FDA; any drug requiring pre-authorization that is proposed for off-label prescribing;
- * Any health product or service that is subject to Investigational Review Board (IRB) review or approval;
- * Any health product or service that the subject of a clinical trial that meets criteria for Phase I, II, or III as set for the by the FDA regulations;
- * Any health product or service whose effectiveness is unapproved based on clinical evidence reported in *peer-reviewed medical literature*.

Id. at 75 (CB 000083).

B. Coventry Denies Mr. Neal’s Request for Certification of a Combined Liver and Kidney Transplant Procedure.

9. On March 16, 2006, Coventry received a telephone call from the University of Wisconsin Hospital inquiring whether Coventry has an alcohol abstinence policy for

transplants. *See* Ralph C. Neal Call Logs Summary for Transplant Related Services, at 2 (CB000163) [Salvo Decl. ¶ 4] (hereinafter “Call Logs Summary”).

10. Coventry advised the University of Wisconsin that its policy requires that candidates have six months of sobriety and be in treatment for substance abuse. *Id.*

11. The 6-month pre-transplant abstinence guideline is also the “normal abstinence period” required by the University of Wisconsin Hospital for alcoholic patients seeking liver transplant and related services. *See* Letter from Anthony D’Alessandro, M.D., Professor of Surgery, Division of Transplantation at the University of Wisconsin, to Dollene Tyler, Coventry/First Health, dated March 21, 2006 [Salvo Decl. ¶ 2(g)] (hereinafter “D’Alessandro Letter”), at 2 (CB 000151).

12. In his March 21, 2006 letter, Dr. Anthony D’Alessandro, M.D., Mr. Neal’s surgeon at the University of Wisconsin, wrote to Coventry to request certification (pre-authorization review) of a combined liver and kidney transplant procedure on Mr. Neal. *Id.*, at 1-2 (CB 000150-151).

13. Dr. D’Alessandro outlined Mr. Neal’s clinical history:

Mr. Neal is a 59 year old with presumed alcoholic cirrhosis who initially presented with recurrent ascites, shortness of breath and leukocytosis through an outside hospital. He was found to be with ascites and acute and chronic renal failure as well as pulmonary edema and pleural effusion. . . . Mr. Neal was discovered to have cirrhosis when he underwent Whipple procedure approximately one year ago.

Id. at 1 (CB 000150).

14. Mr. Neal had only six weeks of pre-transplant abstinence. *Id.* at 2 (CB 000151).

15. Dr. D'Alessandro recognized that Mr. Neal had not abstained from the use of alcohol for six months, despite the fact Mr. Neal had learned that he had cirrhosis of the liver approximately one year earlier: "He is has [*sic*] intermittently continued to consume alcohol since [his alcoholic cirrhosis] diagnosis with his last alcohol consumption approximately six weeks prior to this admission." *Id.*

16. Nevertheless, Dr. D'Alessandro requested coverage for the transplant procedure:

Although Mr. Neal has only been able to demonstrate six weeks of total abstinence prior to this hospitalization, we feel that he is sincere in his willingness to seek out treatment programs in his local area. Although our normal abstinence period is six months we do not feel that is [*sic*] overall health will allow us to wait that total six moth period. We feel that he does have a supportive family in place as well to help him through this recovery process. Right now, we see no technical, medical, infectious or psychosocial contraindications to proceeding and feel that we should place his name to the active liver transplant waiting list.

Id.

17. Following a review of Mr. Neal's clinical records by Coventry's Medical Director Dr. Floyd Shewmake (*see* letter from Coventry to Mr. Burnett dated November 12, 2007 [Salvo Decl. ¶ 9], at 2 (CB 000299) (identifying Dr. Shewmake), Coventry wrote to Mr. Neal on March 23, 2006 to inform him that it was unable to recommend certification of the proposed transplant procedure as "medically necessary," as defined in

the Plan. *See* March 23, 2006 Notification that Mr. Neal's request for certification of his combined kidney-liver transplant procedure had been denied [Salvo Decl. ¶ 5] (CB 000178-180) (hereinafter "Review Notification").

18. Coventry provided a written copy of its Review Notification to Mr. Neal to, among others, the University of Wisconsin Hospital and Dr. D'Alessandro. *Id.* at 3 (CB 000180).

19. Coventry also notified the University of Wisconsin Hospital by phone on March 23, 2006 of the non-certification decision. *See* Call Logs Summary at 2 (CB000164).

C. Mr. Neal Undergoes a Non-Certified Transplant Procedure, and Coventry Denies Multiple Post-Service Transplant and Transplant-Related Claims for Benefits Because They Are Not Covered under the Plan.

20. On April 7, 2006, Mr. Neal underwent the non-certified liver and kidney transplant. *See, e.g.*, Spreadsheet provided to Mr. Neal detailing transplant and transplant-related claims for benefits with dates of service from April 5, 2006 to October 29, 2007, which were denied post-service from April 25, 2006 to November 13, 2007 (hereinafter "Claims Spreadsheet") [Salvo Decl. ¶ 2(b)] , at 2 (CB 000100).

21. On several subsequent occasions, Mr. Neal sought medical treatment and incurred medical costs related to the transplant. *Id.* at 1-19 (CB 000099-117).

22. The Plan does not cover complications arising from any non-covered surgery or treatment. Plan, at 43 (CB 000051).

23. From April 5, 2006 to October 29, 2007, Coventry denied multiple post-service transplant and transplant-related claims submitted by Mr. Neal. *See* Claims Spreadsheet, at 1-19 (CB 000099-117).

24. The billed charges on these transplant-related denied claims total \$518,388.20 (which includes \$400 deductible). *See* Claims Spreadsheet, at 1-19 (CB 000099-117); Christopher & Banks' determination of Mr. Neal's appeal, in the form of a March 20, 2008 letter to Mr. Neal's counsel George Burnett, Esq., signed on behalf of Christopher & Banks by Harold Sassaman and Mary Madison (hereinafter "Appeal Denial") [Salvo Decl. ¶ 2], at 1 (CB 000001) .

25. During the same period, the Plan paid \$108,598.63 for non-transplant-related items for Mr. Neal. *Id.*

D. Mr. Neal Appeals the Denial of His Multiple Transplant and Transplant-Related Claims.

26. The Plan includes a 180-day appeal deadline: "Within 180 days of receipt of the notice of the claim denial or clinical non-certification, you may request, in writing, that the plan conduct a review of the processed claim." Plan, at 64 (CB 000072).

27. The Plan advises participants that "[r]equests for appeal which do not comply with these procedures [e.g., the 180-day deadline] will not be considered, except in extraordinary circumstances." *Id.*

28. The Review Notification, for example, also repeats the 180-day appeal period. *See* Review Notification at 2 (CB 000179).

29. On September 26, 2007, Coventry received a letter dated September 19, 2007, from Neal's attorney George Burnett, Esq., Liebmann, Conway, Olejniczak & Jerry, S.C. ("Liebmann Conway"). *See* September 19, 2007 Letter (CB 000294-95.) [Salvo Decl. ¶ 7].

30. In this September 19, 2007 letter, Mr. Neal, through his attorneys, notified Christopher & Banks "that Ralph C. Neal is appealing the clinical non-certification of the above-described kidney transplant surgery." Sept. 19, 2007 Letter, at 1 (CB 000294.)

31. In response, Coventry informed Liebmann Conway that the appeal should be from the denial of claims since Mr. Neal had already undergone the transplant surgery. *See* letter from Mr. Burnett to Coventry, dated October 30, 2007, with an October 31, 2007, fax header [Salvo Decl. ¶ 8] (hereinafter "October 31, 2007 Letter"), at 1 (CB 000296-297).

32. Coventry advised Liebmann Conway of the 180-day deadline. Coventry's February 26, 2008 recommendation to Christopher & Banks that the Plan deny Mr. Neal's appeal of the denial of his transplant-related claims for benefits [Salvo Decl. ¶ 3], at 2 (CB 000306).

33. On October 31, 2007, Coventry received a letter from Mr. Burnett dated October 30, 2007. *Id.*

34. This letter notified Coventry that Mr. Neal was appealing "the denial of claims for medical treatment expenses for the . . . kidney transplant surgery." October 31, 2007 Letter, at 1 (CB 000296).

35. The October 30, 2008 letter also requested that the Plan treat the denial-of-benefits appeal as having been requested on September 19, 2007, the date of the prior letter seeking to appeal the non-certification. *Id.*

36. Coventry and Mr. Burnett exchanged several rounds of correspondence following this letter. *E.g.*, Letter from Coventry to Mr. Burnett dated November 12, 2007 (CB 000298-99) [Salvo Decl. ¶ 9]; Letter from Mr. Burnett to Coventry dated November 26, 2007 (CB 000300-301) [Salvo Decl. ¶ 10] (hereinafter “Nov. 26, 2007 Letter”); Letter from Coventry to Mr. Burnett dated December 3, 2007 (CB 000302-303) [Salvo Decl. ¶ 11].

37. By letter dated November 26, 2007, Mr. Burnett again asked Coventry to confirm “that the appeal would be considered filed with your office as of September 19, 2007,” repeating — “Would you please confirm that the date Coventry is considering this matter as having been appealed is September 19, 2007.” Nov. 26, 2007 Letter, at 1 (CB 000300).

E. Coventry Request and Receives an Independent Consult from Dr. David K. Imagawa, M.D, Who Recommends that Mr. Neal’s Transplant and Transplant-Related Services Do Not Meet the Plan Definition of “Medically Necessary.”

38. On January 23, 2008, Coventry received 1,977 pages of Mr. Neal’s medical records from University of Wisconsin Hospital and Clinics, and and Bellin Health – Ashwaubenon, where Mr. Neal received certain post-transplant care, accompanied by a cover letter dated January 17, 2008. *See* Letter from Mr. Burnett to Coventry dated

January 17, 2008 (CB 000304) [Salvo Decl. ¶ 12]; Feb. 26, 2008 Recommendation, at 3 (CB 000307).

39. On February 14, 2008, Coventry submitted Mr. Neal's appeal to Dr. David K. Imagawa, M.D., a board-certified surgeon, for an outside independent review of Neal's transplant based on the appeal documentation, the clinical documentation from University of Wisconsin Hospital and Clinics and Bellin Health, and the Plan language. Feb. 26, 2008 Recommendation, at 3 (CB 000307); Written Consult Report Prepared by Dr. David K. Imagawa, M.D., dated February 22, 2008 [Salvo Decl. ¶ 2(d)] (hereinafter "Imagawa Report"), at 1-3 (CB 000123-125) .

40. Dr. Imagawa performed a thorough medical review and prepared a written report dated February 22, 2008. *Id.*

41. Dr. Imagawa's report concluded that Neal's transplant did not meet the criteria to be considered "medically necessary" as defined in the Plan. Imagawa Report, at 1 (CB 000123).

42. He provided the following clinical summary:

The patient is a 59-year-old male with liver and kidney failure secondary to alcohol abuse. He was initially seen at University of Wisconsin on December 16, 2005. At that time he presented with ascites. He was noted to have been abstinent for six weeks. His previous history was significant for Whipple procedure performed in March of 2005 for "a mass" (presumably chronic pancreatitis from alcohol).

The next encounter is on March 10th when he was transferred from an outside hospital with ascites, hyperbilirubinemia, renal failure and a Model for End-Stage Liver Disease (MELD) score of 49. According to multiple dictations his last drink of alcohol was six weeks prior to admission. A

transplant work up was instituted and a request for authorization submitted. The request was denied by First Health on March 22nd “By definition this patient must be considered an active alcohol user and is not a transplant candidate.”

Nevertheless, the University of Wisconsin proceeded with a combined liver-kidney transplant on April 7th, 2006. The patient’s postoperative course was complicated by multiple medical issues. As of August of 2007 the patient was doing well and according to the notes was abstinent (although no toxicology screens were provided).

Id. at 2 (CB 000124).

43. Dr. Imagawa’s explained his rationale for recommending that Neal’s transplant did not meet the criteria to be considered “medically necessary” as defined in the Plan as follows:

Liver transplantation for alcoholic liver disease has always been a difficult issue. Based on early data on recidivism (University of Pittsburgh, University of Michigan) virtually all liver transplant programs and insurance companies have instituted a minimum six-month period of abstinence.

Many articles continue to insist that the “six month rule” is arbitrary. Even the United Network for Organ Sharing (UNOS) listing criteria do not require a six month abstinent period. However, with that being said, all proponents of a flexible policy advocate the significance of the interaction between patient, transplant psychiatrist, transplant social worker and transplant coordinator. The current patient did not even undergo a psychiatric or social work evaluation. “Nurse coordinator states they do not feel the patient needs a psychiatric evaluation or clearance since he does not have any history of mental illness.”(page 886).

Based on the notes provided it is quite unlikely that that patient had any insight into his disease process in

April of 2006. He underwent surgery for pancreatitis secondary to alcohol in March of 2005 and continued to drink.

Id. at 1-2 (CB 000123-124).

44. Dr. Imagawa's report referenced a publication of the National Institute On Alcohol Abuse and Alcoholism, entitled *Liver Transplantation for Alcoholic Liver Disease*, which Christopher & Banks later obtained and reviewed. *Id.* at 2 (CB 000124); Appeal Denial, at 2 (CB 000002).

F. Christopher & Banks Considers Mr. Neal's Appeal and Issues Its Final Determination Concluding that Neal's Appeal is Untimely in Significant Part and Affirming that His Multiple Transplant and Transplant-Related Claims Are Not Covered by the Plan.

45. On March 20, 2008, Christopher & Banks denied Mr. Neal's appeal. Appeal Denial, at 1-4 (CB 000001-04).

46. Christopher & Banks notified Mr. Neal of the denial in the form of a letter to Mr. Burnett signed on behalf of Christopher & Banks, as Plan Administrator. *Id.*

1. Christopher & Banks Determined that Mr. Neal's Appeal Was Untimely, in Significant Part, and Timely, in Part

47. Christopher & Banks agreed to regard Mr. Neal's appeal, as Mr. Burnett requested, as having commenced September 19, 2007. *Id.* at 1 (CB 000001).

48. In accordance with the Plan's 180-day appeal deadline, Christopher & Banks treated as timely Mr. Neal's appeal of transplant-related denials processed on or after March 14, 2007. *Id.*

49. Conversely, Christopher & Banks treated as untimely Mr. Neal's appeal of transplant and transplant-related denials processed from April 25, 2006 to March 1, 2007,

with the exception of previous appeals Mr. Neal had submitted on May 20, 2006 and March 9, 2007 relating to ambulance and transport services in early May 2006 (with charges totaling \$14,104.55). *Id.*

50. To account for the gap between the date a claim would have been processed and the date Mr. Neal would have received the claim denial, which triggers the 180-day period, Christopher & Banks treated as timely Mr. Neal's appeal of all claim denials that were processed on or after March 14, 2007, allowing a generous 9 days for mailing, etc., beyond the 180 days. *Id.*

51. With the exception of appeals Mr. Neal had submitted previously on May 20, 2006 and March 9, 2007 relating to ambulance and transport services in early May, 2006 (with charges totaling \$14,104.55), Christopher & Banks treated as untimely Mr. Neal's appeal of all claims that were denied for transplant-related services received on or about April 7, 2006 and thereafter, which were processed during the period April 25, 2006 to March 1, 2007. *Id.*

52. Christopher & Banks explained its rationale for this decision:

As explained in Coventry's December 3, 2007 letter to you, under the terms of the Plan (see p. 64 of the enclosed Plan), if Mr. Neal desired to appeal the denial of a claim after receiving service, he would have to submit an appeal within 180 days of receipt of the notice of claim denial. Because, as your November 26, 2007 letter to Coventry requests, we are treating the current appeal as having been requested on September 19, 2007, the date of your first letter, the current appeal is timely with respect to post-service claim denials received by Mr. Neal within 180 days before September 19, 2007. In other words, the appeal raised by your September 19, 2007 letter is timely with

respect to claim denials received by Mr. Neal on or after March 23, 2007. . . Because there is a small gap between the date a claim is processed, and the date a claim denial would be received by Mr. Neal, which triggers the 180-day period, we are treating as timely within the 180-day period all claims denied that were processed on or after March 14, 2007 . . . , which provides 9 days for mailing etc. beyond the 180 days.

Conversely, with the exception of appeals submitted on May 20, 2006 and March 9, 2007 relating to ambulance and transport services in early May, 2006 (with charges totaling \$14,104.55), the current appeal is untimely with respect to all claims that were denied for transplant-related services received on or about April 7, 2006 and thereafter, which were processed during the period April 25, 2006-March 1, 2007 (see spreadsheets pages 1-14).

As the Plan states (p. 64), “[r]equests for appeal which do not comply with these procedures [here the 180-day deadline] will not be considered, except in extraordinary circumstances.” Consistent with the plan administrator’s obligation to the terms of the Plan, we are hereby denying as untimely the current attempted appeal of the denials of transplant-related services that processed during the period April 25, 2006-March 1, 2007 (with the exception of the earlier ambulance appeals noted above). In accordance with the Plan, you are allowed to present evidence why the appeal should not be rejected as untimely.

Id. at 1-2 (CB 000001-02).

2. Christopher & Banks Determined that Mr. Neal’s Transplant and Transplant-Related Services Are Not Covered By the Plan

53. Christopher & Banks also determined that Mr. Neal’s transplant and transplant-related services are not covered by the terms of the Plan because they are not “medically necessary,” as defined in the Plan. *Id.* at 2-3 (CB 000002-03).

54. To determine whether Mr. Neal's transplant and transplant-related services are "medically necessary" as defined in the Plan, Christopher & Banks considered the information he submitted, the file materials from Coventry, and a number of other relevant items. *Id.* at 2 (CB 000002).

55. Christopher & Banks determined that "Mr. Neal's transplantation was and is inconsistent with well-recognized scientific and medical guidelines for liver transplant in alcoholic patients, which are accepted by the Plan." *Id.* at 3 (CB 000003).

56. Christopher & Banks considered the information Mr. Neal submitted, the file materials from Coventry, and a number of other items:

- Christopher & Banks consulted with Dr. Shewmake, to whom Mr. Neal's transplant had been submitted for certification (pre-authorization review).
- Christopher & Banks reviewed five pages of medical guidelines for adult liver transplant that it received from Dr. Shewmake.
- Christopher & Banks reviewed Dr. Imagawa's independent consult report.
- Dr. Imagawa's report referenced a publication of the National Institute On Alcohol Abuse and Alcoholism, entitled "Liver Transplantation for Alcoholic Liver Disease," which Christopher & Banks obtained and reviewed.
- Christopher & Banks reviewed a February 2008 article in the journal *Liver Transplantation* entitled "Meta-Analysis of Risk For Relapse to Substance Abuse After Transplantation of the Liver or Other Solid Organs."
- Christopher & Banks reviewed recognized patient selection criteria for liver transplant for alcoholic patients, as reflected in the above items and others, including, for example, the March 21, 2006 letter to Coventry on Neal's behalf from Dr. D'Alessandro.

Id.

57. The five pages of medical guidelines for adult liver transplant that Christopher & Banks received from Dr. Shewmake include as an additional indication for transplant “No smoking, drugs, or alcohol for at least 6 months prior to transplant,” and include as an absolute contradiction, “Active alcohol and/or substance abuse with recidivism.” *Id.*; Liver Transplant Guidelines that Christopher & Banks received from Coventry’s Medical Director Dr. Floyd Shewmake, M.D., J.D. [Salvo Decl. ¶ 2(c)], at CB 000119 & 122.

58. Coventry, the Plan’s contract administrator, has a policy requiring that transplant candidates have 6 months of sobriety and be in treatment for substance abuse. Appeal Denial, at 3 (CB 000003).

59. Dr. Shewmake informed Christopher & Banks that he has not deviated from the 6-month pre-transplant abstinence guideline in other cases. *Id.*

60. Mr. Neal’s surgeon at the University of Wisconsin advised the Plan that six months of pre-transplant abstinence is the “normal abstinence period” at the University of Wisconsin. *Id.*; D’Alessandro Letter, at 2 (CB 000151).

61. The February 2008 article in *Liver Transplantation* confirms that “transplant programs strive to apply the ‘6-month rule’ as a key criterion for patient selection.” Appeal Denial, at 3 (CB 000003); Dew et al., “Meta-Analysis of Risk for Relapse to Substance Use After Transplantation of the Liver or Other Solid Organs,” 14 *Liver Transplantation* 159 (2008) [Salvo Decl. ¶ 2(f)], at 168 (CB 000145).

62. Based on all the evidence, Christopher & Banks determined there was widespread recognition of the 6-month abstinence guideline in the national transplant

research community and that the Plan should continue to accept and apply the guideline. Appeal Denial, at 3 (CB 000003).

63. Christopher & Banks concluded that Mr. Neal's transplant procedure was inconsistent with the 6-month abstinence guideline because he had been abstinent for only *six weeks* before the admission that resulted in the transplant. Appeal Denial, at 2-3 (CB 000002-03).

64. Christopher & Banks explained the evidence it considered and the process by which it reached its decision:

The liver transplant guidelines utilized by Dr. Shewmake in 2006 specify that an indication for transplant is no alcohol for at least six months prior to transplant. Dr. Shewmake also informed us that he has not deviated from this guideline in other cases. When Mr. Neal was hospitalized in advance of the transplant, it was noted that he had intermittently continued to use alcohol since he was discovered to have cirrhosis approximately a year ago, with his last usage claimed to be approximately six weeks before the admission that resulted in transplant. The 6-month pre-transplant abstinence guideline is also the "normal abstinence period" required by the University of Wisconsin, where the transplant was performed (see Dr. D'Alessandro's March 21, 2006 letter). The February 2008 article in liver Transplantation makes clear that there is widespread use of the 6-month guideline. Page 168 of the article notes that "transplant programs strive to apply the '6-month rule' as a key criterion for patient selection." Given the widespread recognition of the 6-month guideline in the national transplant research community, that guideline will continue to be accepted and applied by the Plan.

Id. at 3 (CB 000003).

65. Christopher & Banks considered the 6-month pre-transplant abstinence guideline in relation to the following portion of the Plan's definition of "medically necessary":

Medically necessary services and/or supplies the plan administrator determines, in the exercise of its discretion, to be:

(4). Consistent in type, frequency and duration of treatment with scientifically-based guidelines of national medical research, professional medical specialty organizations or governmental agencies that are accepted by the plan.

Id.

66. Because Mr. Neal's transplant procedure was not consistent with the Plan-accepted 6-month pre-transplant abstinence guideline, Christopher & Banks concluded that the procedure did not meet the Plan's definition of "medically necessary." *Id.* at 2-3 (CB 000002-03).

67. Christopher & Banks also concluded that Mr. Neal's transplant, following only six weeks of pre-admission claimed abstinence, was not covered under the Plan because the effectiveness of such a transplant was unproven based on clinical evidence reported in peer-reviewed medical literature, and thus the transplant was "investigational/experimental" as defined in the Plan:

Mr. Neal's transplantation with only six weeks of pre-admission claimed abstinence is also not covered under the Plan because such transplantation is investigational or experimental as defined in the Plan

(p. 75). Specifically, the effectiveness of such transplant is unproven based on clinical evidence reported in peer-reviewed medical literature. There is a lack of consensus in the medical research community that transplantation with such limited pre-transplant abstinence is indicated. We recognize that there are physicians on both sides of this issue, as reported in the National Institute article, but this division, together with the 6-month guideline, demonstrates the unproven nature of transplants with limited pre-transplant abstinence.

Id. at 3 (CB 000003).

Dated: January 20, 2009

DORSEY & WHITNEY LLP

By s/ Glenn M. Salvo

Glenn M. Salvo #1046178

Timothy E. Branson #0174713 MN

Suite 1500, 50 South Sixth Street

Minneapolis, MN 55402-1498

Telephone: (612) 340-2600

Attorneys for Defendants Christopher & Banks Comprehensive Major Medical Plan, Christopher & Banks Group Disability Income Insurance Plan, and Christopher & Banks, Inc.